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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,289	10/09/2003	F. Barry Bays	702.113	9339

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WRIGHT MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No.	Applicant(s)
	10/682,289	BAYS ET AL.
	Examiner	Art Unit
	Ruth A. Davis	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on October 25, 2007 has been received and entered into the case. Claims 23 – 44 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 23 – 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler (US 6723131) in view of Wironen et al. (US 2003/0180262 A1).

Applicant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. The end caps and filter membranes have removable sealing caps, wherein a second sealing cap provides an air tight environment; and washers are disposed between the end caps and tube ends. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter; the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end.

However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein the end caps have removable sealing caps, or wherein washers are used between the tube and end caps. However, in the response filed on March 14, 2006 to the election restriction requirement mailed on February 14, 2006, applicant clearly admitted on the record that the groups of the various inventions were obvious over each other under the meaning of 35 USC 103. Specifically, in that the inventions of a bone graft material, methods for making the material and the claimed apparatus for holding or preparing the bone graft material are obvious over each other under the meaning of 35 USC 103. Standard examination practice dictates that when an applicant traverses restrictions on the grounds that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence of record showing the inventions to be obvious variants **or** clearly admit on the record that this is the case. Furthermore, in either case, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions. This practice has long been established and is further supported by the MPEP (form paragraph 8.21). In the instant application, applicant clearly admitted on the record that the inventions were obvious variants over each other. Thus, in finding the inventions of a bone graft material, methods for making the material and an apparatus for housing/preparing the material, those inventions and/or limitations not specifically disclosed by the art are rendered obvious under 35 USC 103, as admitted by applicant. While claims to the bone graft and methods for making the graft have been canceled, applicant's earlier admission remains applicable over limitations of the apparatus not disclosed by the cited art. Therefore, while the references do not teach the apparatus with removable sealing caps and washers, the limitations are rendered obvious.

4. Claims 23 – 29, 32 and 35 – 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe et al. (US 6736799 B1).

Applicant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. The end caps and filter membranes have removable sealing caps, wherein a second sealing cap provides an air tight environment. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter;

the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end. However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein the end caps have removable sealing caps. However, at the time of the claimed invention, the end caps of apparatuses for making bone graft composites were commonly sealed in the art. In support, Erbe teaches an apparatus for making bone composite materials wherein the end caps are closed (or sealed) to seal the material chamber (or tube with graft material) (col.3 line 9-25, claims). While the reference does not expressly teach the sealing cap in addition to the end cap, the reference certainly suggests to one in the art the desire to seal the graft tubes. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Erbe, to include a sealing cap on the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

5. Claims 23 – 27, 30 – 33, 36 – 38 and 40 - 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Willard et al. (US 4846174).

Applicant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. Washers are disposed between the end caps and tube ends. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter; the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end. However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein washers are used between the tube and end caps. However, Muschler teaches that the end caps are removable to the tube via threaded connections, or any other known connection (col.7 line 12-14). At the time of the claimed invention, it was known to include washers between caps and threaded connections for their aid in equalizing pressure distribution, securing placement and ensuring air tightness. In support, Willard teaches columnar tubes wherein a threaded end has a removable cap and washer placed in between to secure the assembly (col.11 line 55-col.12 line 14, figure 1). Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Willard, to include a washer in the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

6. Claims 23 – 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Muschler in view of Wironen and further in view of Erbe and Willard.

Applicant claims an apparatus for preparing a bone graft composite comprising a tube with a first and second end; a first removable end cap which allows passage of bone marrow aspirate delivery member and attachment to a bone marrow aspirate delivery member; a second removable end cap which allows communication between the tube and a filter and is configured to attach with a filter; a removable filter membrane attached to the second end cap; a filter in the membrane that prevents bone marrow aspirate to flow through while allowing air to flow through; and a bone graft in the tube. The graft material is selected from calcium sulfate, calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix, specifically tri-calcium phosphate; the bone graft material is porous to bone marrow aspirate; or the bone graft material comprises a plurality of small bone pieces. The end caps and filter membranes have removable sealing caps, wherein a second sealing cap provides an air tight environment; and washers are disposed between the end caps and tube ends. The apparatus further comprises bone marrow aspirate that is introduced via the first end and having had air expelled through the filter; the bone marrow aspirate is allowed to coagulate in the tube after contact with the bone graft material; and the bone graft material is substantially saturated with the aspirate. The first end cap is configured for attachment to a syringe.

Muschler teaches an apparatus for preparing a bone graft composite (abstract), the apparatus comprising a tube with a first and second end (figures), removable end caps (col.7 line 11-14) that may allow for passage of a syringe (or a bone marrow aspirate delivery member) (col.7 line 25-30) or attachment to a screen (or filter) membranes (or end caps that allow communication with filters and bone marrow aspirate delivery members) (col.7 line 15-19); and a bone graft material therein (col.6 line 59-64). The bone graft material may be calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite, demineralized bone matrix, and mineralized bone matrix (col.4 line 13-55); is porous to marrow aspirate (col.4 line 13-15, col.3 line 38-45); or may comprise a plurality of small bone pieces (col.4 line 50-col.5 line 20). The bone marrow aspirate is not anticoagulated, but is allowed to clot (or coagulate) during mixing (or substantially saturating) with the graft material (or within the tube) (col.8 line 51-54).

Muschler does not teach the apparatus wherein the filter membrane prevents aspirate passage while allowing air to pass through. However, Wironen teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045). Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

The combined teachings of the references do not specifically teach the apparatus wherein the aspirate is introduced via a first end having air expelled through the filter of the second end. However Muschler does teach the aspirate being loaded via the first end by means known in the art (col.7 line 39-46), and that the second end may contain a filter membrane. Further, Wironen teaches the advantages of using membranes that prevent passage of aspirate while allowing air to pass through (0045). Thus, the combined teachings of Muschler and Wironen clearly suggest to one in the art to load the tube through one end while expelling air through the other.

The references do not teach the apparatus wherein the end caps have removable sealing caps, used or wherein washers are used between the tube and end caps. However, at the time of the claimed invention, the end caps of apparatuses for making bone graft composites were commonly sealed in the art. In support, Erbe teaches an apparatus for making bone composite materials wherein the end caps are closed (or sealed) to seal the material chamber (or tube with graft material) (col.3 line 9-25, claims). While the reference does not expressly teach the sealing cap in addition to the end cap, the reference certainly suggests to one in the art the desire to seal the graft tubes. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Erbe, to include a sealing cap on the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite. In addition, it was further known to include washers between caps and threaded connections for their aid in equalizing pressure distribution, securing placement and ensuring air tightness. In support, Willard teaches columnar tubes wherein a threaded end has a removable cap and washer placed in between to secure the assembly (col.11 line 55-col.12 line 14, figure 1). Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by common practice, as evidenced by Willard, to include a washer in the apparatus of Muschler with a reasonable expectation for successfully obtaining an apparatus effective to prepare a bone graft composite.

Response to Arguments

Applicant argues that there is no motivation to improve the apparatus of Muschler with Wironen; that the references do not teach all of the claimed elements; that the combination destroys the function of Muschler; that a prima facie case has not been made; and that the references do not teach a filter that retains bone marrow aspirate (BMA) while expelling air. Applicant argues that Muschler teaches away from removing air by allowing BMA to pass while obtaining an enriched cell population. Applicant further argues that Wironen does not teach air removal improves forming a bone graft material; that the reference teaches minimalizing air bubbles not removing air; and a different apparatus. Applicant additionally argues that there is no reason to combine the references; that the examiner uses improper hindsight; that a use is not claimed; and that the missing elements cannot be remedied by an admission in response to a restriction requirement. Applicant reiterates previous arguments that a prima facie case of obviousness can not be based on applicant's admission that the different inventions are obvious over each other in response to an election requirement. Applicant finally states that the supporting references do not make up the deficiencies of Muschler and Wironen.

However, these arguments fail to persuade for the following reasons. Regarding the motivation to combine the references, the rejections clearly state that Wironen teaches that it is desirable to remove air from the paste components before, during or after reconstitution is conducted (0045). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the filter of Wironen in the apparatus of Muschler for the disclosed desirability for removing air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

Regarding elements not disclosed by the cited references, it is noted that in the response to an election restriction mailed on February 14, 2006, applicant clearly admitted on the record that the various inventions of an apparatus, methods for making a bone graft, and a bone graft were obvious over each other under the meaning of USC 103 (response filed March 14, 2006). Moreover, as admitted by applicant, a bone graft, method for making a bone graft and the apparatus are obvious over each other under the meaning of USC 103. Thus, a disclosure of a bone graft would render obvious the inventions of an apparatus and methods for making a bone graft obvious under USC 103. It is reiterated that if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions. This practice has long been established and is further supported by the MPEP (form paragraph 8.21). Since applicant clearly admitted on the record that the inventions were obvious variants over each other, finding the inventions of a bone graft material, methods for making the material and an apparatus for housing/preparing the material renders those inventions and/or limitations not specifically disclosed by the art obvious under 35

USC 103, as previously admitted by applicant. While claims to the bone graft and methods for making the graft have been canceled, applicant's earlier admission remains applicable over limitations of the apparatus not disclosed by the cited art. Therefore, while the references do not teach the apparatus with removable sealing caps and washers, the limitations are rendered obvious. Furthermore, it is noted that supporting references Erbe and Willard provide teachings of the missing elements not specifically disclosed by Muschler or Wironen.

Regarding applicant's assertions that the combination destroys the function of Muschler, it is noted that applicant has failed to assert how the apparatus of Muschler is destroyed. Regarding the assertions that an air filter that allows air to pass and not BMA is not disclosed, it is maintained that the teachings of Wironen suggest to one in the art that it is advantageous to remove air before, during or after reconstitution of bone pastes (or bone graft materials). Wironen specifically teaches apparatuses for making bone graft composites (abstract, figures), wherein one end has a filter membrane attached to prevent passage of bone paste components (or aspirate and/or graft materials) while expelling air from the tube (0045), thereby teaching a filter that allows air to pass and not bone graft materials, or BMA. Thus, the combination of Muschler and Wironen suggest to one in the art that it is desirable to remove air from the bone graft composite material during mixing (0045). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Wironen to use a filter that prevents passage of bone paste components (or aspirate and/or graft materials) while expelling air with a reasonable expectation for successfully obtaining an apparatus for making bone graft composites.

Regarding the asserted teachings away from the claimed invention, it is noted that Muschler neither teaches that air should be retained in the BMA, nor that air is beneficial to the cell population. Furthermore, the combined teachings of Muschler and Wironen suggest that air removal is desirable and that a filter to allow air passage and not BMA would benefit the apparatus of Muschler.

Regarding the teachings of Wironen, the reference specifically teaches air bubbles should be expelled, or that air is removed, from the bone graft materials, or BMA (0045). Furthermore, the reference is relied upon to evidence the need for removal of air, and in turn a filter for allowing air to pass without allowing BMA to pass from the apparatus of Muschler.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding the confusion about the asserted use, it is noted that applicant argues the instant apparatus is used during surgery, not for storing bone graft materials. Thus, while the claims do not specifically limit such a use, the use has been, and is currently argued by applicant. Moreover, it is reiterated that the arguments are not commensurate in scope with the claims. It is noted that the intended use (in the instant case, an argued use) of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Regarding applicant's assertions that previous admissions can not be used against applicant, it is reiterated that if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions. This practice has long been established and is further supported by the MPEP (form paragraph 8.21). Since applicant clearly admitted on the record that the inventions were obvious variants over each other, finding the inventions of a bone graft material, methods for making the material and an apparatus for housing/preparing the material renders those inventions and/or limitations not specifically disclosed by the art obvious under 35 USC 103, as previously admitted by applicant. While claims to the bone graft and methods for making the graft have been canceled, applicant's earlier admission remains applicable over limitations of the apparatus not disclosed by the cited art. Therefore, while the references do not teach the apparatus with removable sealing caps and washers, the limitations are rendered obvious.

Finally, it is noted that supporting references Erbe and Willard provide teachings of the missing elements not specifically disclosed by Muschler or Wironen.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

January 4, 2008